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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,944	10/31/2000	Hiroshi Fukuda	20498	1795

151 7590 05/20/2003

HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
NUTLEY, NJ 07110

EXAMINER

MORRIS, PATRICIA L

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 05/20/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/702,944

Applicant(s)

Fukuda et al

Examiner

P. Morris

Group Art Unit

1625

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-9, 14-18, 22, 23, 26, 27, 30 + 31 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-9, 14-18, 22, 23, 26, 27, 30 + 31 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

DETAILED ACTION

Claims 1-9, 14-18, 22, 23, 26, 27, 30 and 31 are under consideration in this application.

Election/Restriction

Again, this application has been examined with regard to the elected compound wherein Q represents (2R,3R)-3-[4-(4-cyanophenyl)thiazol-2-yl]-2-(2,5-difluorophenyl)-1-(1H-1,2,4-triazol-1-yl)-butan-2-ol, R³ is (optionally substituted) pyridin-2-yl and R¹, R² and X as set forth in claim 1, exclusively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-9, 14-18, 22, 23, 26 and 27, 30 and 31 are rejected under 35 U.S.C. 102 (e) and/or (f) as being anticipated by Hayase et al. for the reasons set forth in Paper no. 7.

Again, the references specifically recite the instant compound.

The precursor and final product are not different products, regardless of differences in their activity and efficacy. See *Marion Merrell Dow Inc v. American Cyanamid Co.*, 36 USPQ2d 1036. Hence, the instant compound is deemed to be anticipated therefrom.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 14-18, 22, 23, 26, 27, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayase et al. in view of Hudyma et al. and Davidsen et al. for the reasons set forth in Paper nos. 7 and 14.

As set forth in Paper nos. 7 and 14, Hayase et al. disclose the final product having the same use. Note compound in lines 5-6 in column 5 therein. Further Hudyma et al. teach that analogous amine salts of triazoles similar to those of the claimed invention retained the activity associated with the final products, whereas Davidsen et al. teach that pyridine salts are known to be extremely soluble. In view of the structural similarity between the compounds of the instant claims and those of Hayase et al. and that the substituent connected with the differentiating feature is lost *in vivo*, one of ordinary skill in the art would expect that the claimed compounds would have antifungal activity. It is well settled that the final product and its precursor are not different products, regardless of differences in their activity and efficacy. *Marion Merrell Dow c. V. American Cyanamid Co.*, supra.

Again, the Declaration of Unemda, while interesting, is of little if any probative value because it fails to include the **final** product and the elected compound. The prior art compound tested is not the closest prior art compound. Moreover, the claims are directed to using the instant compounds for the treatment of **fungicidal** infections. Also note page 35 of the specification. The declaration is silent as to whether the compounds treat any **fungal** infection.

Further, the declaration is not commensurate in scope with the claims. It is expected that the final product and its precursor will possess fungicidal activity. No unexpected or unobvious results are noted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The term acyl, either alone or in a combined term, is employed in claims 3 and 4 with no indication given as to what the acyl groups really are.

One should be able, from a reading of the claims, determine what that claim does or does not encompass.

The written description is considered inadequate here in the specification. Conception of the intended acyl groups should not be the role of the reader. Applicants should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 USC 112, first paragraph. If you (the public) find that it works, I claim it, is not a proper basis of patentability. In re Kirk, 153 USPQ 48, at page 53.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 14-18, 22, 23 and 26 are rejected under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The plural "s" on compounds in claims 2-9, 14-18, 22 and 23 makes the claims read on mixtures rather than specific compounds.

Claim 14 does not further limit Q because Q can only be 3-[4-(4-cyanophenyl)thiazol-2-yl]-2-(2,5-difluorophenyl)-1-(1H-1,2,4-triazol-1-yl)-butan-2-ol in claim 1.

Claim 26 is an improper Markush group because it is not in alternative language. It omits either an "or" or an "and".

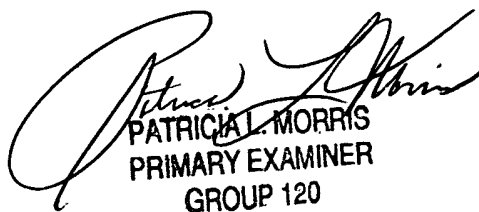
The term trifluoromethoxy for R³, R⁴ and R⁵ is misspelled in claims 1 and 5.

Conclusion

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Morris whose telephone number is (703) 308-4533. The examiner can normally be reached Mondays through Fridays.

plm
May 14, 2003


PATRICIA L. MORRIS
PRIMARY EXAMINER
GROUP 120